DEC - 3 2010

510(k) Summary

Manufacturer:	GS Medical Co. Ltd. 12F Kolon Digital Tower Aston, 505-14 Gasan-Dong Geumcheon-gu, Seoul, Korea
Date:	September 3, 2010
Submitted by:	GS Medical Co. Ltd
Company Contact	Dong Young Kim +82-2-2082-777 +82-2-2082-7778 (FAX)
US Agent Information	Orgenix LLC Mr. Donald W. Guthner 111 Hill Road Douglassville, PA 19518 +1-646-460-2984 +1-484-363-5879 (FAX)
Classification Name:	Intervertebral Body Fusion Device
Common/Usual Name:	Intervertebral Body Fusion Device, IBF Device
Proprietary Name:	AnyPlus ALIF PEEK Lumbar Cage AnyPlus PLIF PEEK Lumbar Cage AnyPlus TLIF PEEK Lumbar Cage
Performance standards:	The GS Medical AnyPlus PEEK Lumbar Cage was non-clinically tested according to the ASTM 2077-03 and ASTM F2267-04 performance standards.
Classification no.:	21 CFR 888.3080 MAX – Intervertebral body fusion device Class II
Substantial Equivalence:	Substantial equivalence for the *GS Medical AnyPlus PEEK Lumbar Cage* is based on its similarities in indications for use, design features, operational principles and material composition when compared to the predicate devices cleared under the following submissions: • P960025 - Brantigen Interbody Fusion Cage, DePuy Spine • K090887 - ORIO-TL TLIF, ORIO-PL PLIF, ORIO-AL ALIF Intervertebral Body Fusion Cage, SpineCraft, LLC

Predicate Devices:	The subject device is substantially equivalent to similar previously cleared devices.
Device Description:	The *GS Medical AnyPlus PEEK Lumbar Cage* device consists of implants available in various heights and lordotic configurations with an open architecture to accept packing of bone graft material. The implants are made of polyether-ether-ketone (PEEK) body with the x-ray markers made of Titanium alloy (Ti-6Al-4V).
Intended Use:	The AnyPlus PEEK Lumbar Cage is indicated for use with autogenous bone graft in skeletally mature patients with degenerative disc disease ("DDD") at one or two contiguous spinal levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six months of non-operative treatment. These DDD patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s).
Summary of Technological Characteristics	The GS Medical AnyPlus PEEK Lumbar Cage devices are designed for restoring the height of the intervertebral space after resection of the disc. The AnyPlus PEEK Lumbar Cage devices consist of implants available in various heights and lordotic configurations with an open architecture to accept packing of bone graft material. The implants are made of polyether-ether-ketone (PEEK) body with the x-ray markers made of Titanium alloy (Ti-6Al-4V). The intended use, technological characteristics, mode of action and materials of construction are the same as those of the referenced predicate devices
Non-Clinical Testing	The GS Medical AnyPlus PEEK Lumbar Cage devices were tested according to the ASTM 2077, specifically, Static and Dynamic Axial Compression, Static and Dynamic Compression-Shear Testing, Static and Dynamic Torsion Testing Expulsion Testing and Static Subsidence testing under Axial Compression, per ASTM 2267.
Conclusion	The information discussed above demonstrates that the GS Medical PEEK Lumbar Cage device is effective and performs as well as or better than the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

GS Medical Co., Ltd.
% Orgenix, LLC
Mr. Donald W. Guthner
111 Hill Road
Douglassville, Pennsylvania 19518

SEP 12 2011

Re: K100516
Trade/Device Name: AnyPlus PEEK Lumbar Cages
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVD
Dated: October 21, 2010
Received: October 22, 2010

Dear Mr. Guthner:

This letter corrects our substantially equivalent letter of December 3, 2010.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other

Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEC - 3 2010

Indications for Use

510(k) Number (if known): K100516

Device Name: AnyPlus PEEK Lumbar Cages

Indications for Use:

The AnyPlus PEEK Lumbar Cage is indicated for use with autogenous bone graft in skeletally mature patients with degenerative disc disease ("DDD") at one or two contiguous spinal levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six months of non-operative treatment. These DDD patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s).

Prescription Use __X_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page __ of ___

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100516